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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,114	06/23/2006	Francois Schutze	032013-119	9051
21839	7590	09/11/2006	EXAMINER	
BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/532,114

Applicant(s)

SCHUTZE ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED-STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 and 18 is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4-21-05</u> . | 6) <input type="checkbox"/> Other: _____ |

A Preliminary Amendment filed April 21, 2005 is acknowledged. New claims 9-18 are presented. Claims 7 and 8 are canceled. Accordingly, claims 1-6 and 9-18 are under consideration.

An Information Disclosure Statement filed April 21, 2005 is further acknowledged. The references have been reviewed to the extent each is a proper citation on a U.S. Patent.

A list of co-pending and related applications for the present inventive entity is requested.

The disclosure is objected to for the following informality: In claim 10 the recitation "1H3-receptor" appears to be inadvertent.

Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plachetka, J.R., US 2005/0249811.

Plachetka suggests a medicinal product comprising an oral composition, i.e., a combination of various ingredients, that contains a histamine H2-receptor antagonist and a proton pump inhibitor. See page 2, paragraph [0013] where equivalence is taught among proton pump inhibitors, such as tenatoprazole and, for example, omeprazole or pantoprazole. See page 5, paragraph [0055], where the outermost layer is stated to

contain an acid inhibitor that is preferably an H₂ receptor blocker such as famotidine. See page 9, paragraph [0083], where a fourth layer is disclosed comprising a proton pump inhibitor. There are no examples drawn to a composition solely comprising tenatoprazole and an H₂-receptor antagonist. However, one skilled in the art of formulation chemistry would have been motivated to prepare a medicinal product comprising tenatoprazole and an H₂-receptor antagonist for the purpose of treating an arthritic or inflammatory condition in view of Plachetka's teaching. Such would have been obvious in the absence of evidence to the contrary because Plachetka's teaching is drawn to the inclusion of "an acid inhibitor" in a medicinal product. Both a proton pump inhibitor and a histamine antagonist are described. Since their mechanisms of action as acid inhibitors are different, and since raising the pH of a patient's gastrointestinal tract (the stomach) is one therapeutic endpoint, the skilled artisan would reasonably consider the incorporation of both a proton pump inhibitor and a histamine antagonist in the same medicinal product.

The open language of the present claims allows for the inclusion of any number of additional active agents. The intended use of composition claims confers no patentable weight to the claims. Applicants are not entitled to procure claims based on discovery that a known composition can be adapted to a new use. *In re Hack*, 114 USPQ 161 (CCPA 1957). The determination of an optimal ratio of the active agents, as well as optimal concentrations, are parameters well within the purview of those skilled in the art through no more than routine experimentation.

Claims 17 and 18 appear to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phyllis Spivack

September 2, 2006